PATENT Docket No. 350292001300

#### CERTIFICATE OF HAND DELIVERY

Lhereby certify that this correspondence is being hand filed with the United States Patent and Trademark Office in Washington, D.C. on August 21, 2002.

N. Slaveter

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Masaaki KOSAKA et al.

Serial No.:

10/069,290

Filing Date:

February 25, 2002

For:

**EXPRESSION ENHANCER FOR HM1.24** 

Examiner: to be assigned

Group Art Unit: to be assigned

## RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 USC 371

U.S. Patent and Trademark Office Washington, DC 20231

Sir:

In response to the Notification of Missing Requirements Under 35 USC 371 (copy attached) dated May 2, 2002, applicants submit the following:

- 1. Response to Notification of Missing Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures, diskette containing the nucleotide sequence and/or amino acid sequence disclosures, and a printout of the sequence listing; and
- 2. Missing Requirements filing fee of \$642.00 (\$130 surcharge for declaration submitted after 30 months from priority date and \$12.00 additional claims), and Petition for Extension of Time of 2 months (\$400.00).

When applicants filed the application on February 25, 2002, the number of claims indicated on the National Stage Transmittal Letter were incorrect, resulting in incorrect additional claim fees. Applicants indicated that there were 14 additional total claims (14 x \$18 = \$252), 6 additional independent claims (6 x \$84 = \$504), and multiple dependent claims (\$280). The incorrect total fees enclosed with the Transmittal Letter dated February 25, 2002 was \$1,036. In the Transmittal Letter submitted herewith, the correct claims are as follows:

Total claims 30 - 20 = 10 extra claims x \$18 = \$180

Independent claims 10 - 3 = 7 extra claims x \$84 = \$588

Multiple dependent claims = \$280

Total Additional Claim fees \$1,048

Minus Incorrect Total Claim fees previously paid <u>-\$1,036</u>

CORRECT ADDITIONAL CLAIM FEES \$12.00

In the event that the transmittal letter is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. <u>350292001300</u>.

By:

Respectfully submitted,

Dated: August 21, 2002

Jonathan Bockman Registration No. 45,640

Morrison & Foerster LLP 2000 Pennsylvania Avenue, N.W. Washington, D.C. 20006-1888 Telephone: (202) 778-1601 Facsimile: (202) 263-8396

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	ORM PTO	0.1300 U.S.DE	1 OF COMMERCE PATENT AND TRADEMARK	AT SYS DOCKET NUMBER	
(RI	EN 11-206		ER TO THE UNITED STATES	350292001300	
•			CTED OFFICE (DO/EO/US)	U.S. APPLICATION NO. (If known, see 37 CFR 1.5)	
			ING UNDER 35 U.S.C. § 371	10/0/0 200	
			INTERNATIONAL FILING DATE	10/069,290 PRIORITY DATE CLAIMED	
1.5	CIERNA	ATIONAL APPLICATION NO. PCT/JP00/05617	INTERNATIONAL FILING DATE	FRIORIT DATE CLAUSIED	
			August 22, 2000	August 23, 1999	
TI	TLE OF	FINVENTION	EVEDESCION ENHANCED FOR HMI 24 ANT	ICEN	
Α1	PPLICA	ANT(S) FOR DO EO US	EXPRESSION ENHANCER FOR HM1.24 ANT	IGEA	
	111.10.1	Triangle to the triangle to th	Masaaki KOSAKA et al.		
Aj	pplicant	herewith submits to the United Sta	ates Designated Elected Office (DO/EO/US) the following	tems and other information:	
1	This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.				
2.	This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.				
3.	This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.				
4.		The US has been elected by the expiration of 19 months from the priority date (PCT Article 31).			
5.		A copy of the International App	olication as filed (35 U.S.C. 371(c)(2))		
	a.	is attached hereto (require	d only if not communicated by the International Bureau).		
	b	has been communicated b	y the International Bureau.		
	c.	is not required, as the appl	lication was filed in the United States Receiving Office (R	O/US).	
6.		An English language translation	English language translation of the International Application under PCT Article 19 (35 U.S.C. 371(c)(2)).		
	a.	is attached hereto.			
	b.	has been previously subm	itted under 35 U.S.C. 154(d)(4).		
7.		Amendments to the claims of th	e International Application under PCT Article 19 (35 U.S	.C. 371(c)(3)).	
	a.	are attached hereto (requir	ed only if not communicated by the International Bureau)		
	b.	have been communicated	by the International Bureau.		
•	c.	have not been made; howe	ever, the time limit for making such amendments has NOT	expired.	

#### An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). 10.

### Items 11. to 16. below concern document(s) or information included:

Other items or information:

An Information Disclosure Statement under 37 CFR 1.97 and 1.98.

have not been made and will not be made.

12.		An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13.	×	A FIRST preliminary amendment.
14.		A SECOND or SUBSEQUENT preliminary amendment.
15.		A substitute specification.
16		A change of power of attorney and/or address letter.
17		A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18		A second copy of the published international application under 35 U.S.C. 154(d)(4).
19		A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

diskette containing sequence listing and printout of sequence listing; Petition for Extension of Time of 2 months CERTIFICATE OF HAND DELIVERY

Response to Response to Notification of Missing Requirements Under 35 USC 371 and copy of Notification of Missing Requirements; Response to Notification of Missing Requirements for Patent Applications Containing Nucleotide Sequence and or Amino Acid Sequence Disclosures with

I hereby certify that this correspondence is being hand filed with the United States Patent and Trademark Office in Washington, D.C. on August 21, 2002.

N. Slaveter

20.

11.

				A TYPE AND A NAME OF THE OWNER.	
U.S. APPLICATION NO. 10 069,290		INTERNATION:	•	ATTORNEY'S DOCKET NUMBER 350292001300	
APPLICATION NO PCT JP00 05617			X(7) (1) (1) (1) (1)	CALCULATION	<u></u>
	☐ The following fees are submitted:  BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(5)):				
Neither international p	oreliminary examination f h fee (37 CFR 1.445(a)(2	fee (37 CFR 1.482)	\$1,040 00		
International prelimina	ary examination fee (37 C				
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO					
International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provision of PCT Article 33(1)-(4)					
International prelimina and all claims satisfied	d provisions of PCT Artic	CFR 1.482) paid to USPTele 33(1)-(4)	\$100.00		
	EN		BASIC FEE AMOUNT =	\$	↓_
			ension of Time of 2 months	\$400	↓_
Surcharge of \$130.00 for furnishing the oath or declaration later than □ 20 ■ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).  CORRECT NUMBER OF CLAIMS FILED WITH APPLICATION ON 2/25/02:				\$130	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		├─
Total claims	30 - 20 =	10	x \$18.00	[\$180] see below	$\vdash$
Independent claims	10-3=	7	x \$84.00	[\$588] see below	$\vdash$
	DENT CLAIM(S) (if appl	icable)	+ \$280.00	[\$280] see below	
WODIN BE BEI EN	zivi ezimi(e) (ii uppi		OVE CALCULATIONS =	[\$1048] see below	$\vdash$
☐ Applicant claims small e	\$				
<b>—</b>	,		SUBTOTAL =	*\$12	
		iglish translation later that riority date (37 CFR 1.492		\$	
		TO	TAL NATIONAL FEE =	\$	
		CFR 1.21(h)). The assign CFR 3.28, 3.31). <b>\$40.00</b>		\$	
		TOT	AL FEES ENCLOSED =	\$642.00	$\vdash$
CLAIMS AS INCORREC Total Claims Independent claims		TRANSMITTAL SHEI 14 x \$18 = \$ 252 6 x \$84 = \$ 504	ET FILED 2/25/02		\$
Multiple dependent cl		*** \$\frac{\$ 280}{\$1,036} \)			

- a.  $\square$  A check in the amount of \$ to cover the above fees is enclosed.
- b. Please charge my <u>Deposit Account No. 03-1952</u> in the amount of \$642.00 referencing Docket No. 350292001300 coving the above fees. A duplicate copy of this sheet is enclosed.
- c. 

  The Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment to 

  Deposit Account No. 03-1952. A duplicate copy of this sheet is enclosed.
- d. 

  Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Barry E. Bretschneider Morrison & Foerster LLP 2000 Pennsylvania Avenue, N.W. Washington, D.C. 20006-1888

SIGNATURE

Jonathan Bockman, Registration No. 45,640



### UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Potents, Gox 95.1 United States Patent and Fractorisms Office Washington, LC, 2010 www.aph..co.

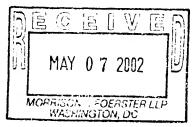
ATTY DOCKET NO. FIRST NAMED APPLICANT U.S. APPLICATION NUMBER NO 350292001300 Masaaki Kosaka J 10 069.290 INTERNATIONAL APPLICATION NO

PCT/JP00/05617

08/22/2000 (6

PRIORITY DATE 1 A FILING DATE 08:23:1999

Barry E Bretschneider Morrison & Foerster 2000 Pennsylvania Avenue N W Washington, DC 20006-1888



**CONFIRMATION NO. 1521** 371 FORMALITIES LETTER \*OC000000008002289\*

Date Mailed: 05/02/2002

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as an Elected Office (37 CFR 1.495):

- U.S. Basic National Fees
- Priority Document
- Assignee Statement
- Biochemical Sequence Diskette
- Biochemical Sequence Listing
- Copy of IPE Report
- Copy of references cited in ISR
- Copy of the International Application
- Copy of the International Search Report
- English Translation of the IA
- Information Disclosure Statements
- Oath or Declaration
- Request for Immediate Examination

The following items MUST be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

• \$130 Surcharge for providing the oath or declaration later than the appropriate 30 months months from the priority date (37 CFR 1.492(e)) is required.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTH FROM THE DATE OF THIS NOTICE OR BY 22 or 32 MONTHS (where 37 CFR 1.495 applies) FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Additionally the following defects have been observed:

The following items MUST be furnished within the period set forth below:

- The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821-1.825 for the following reason(s):
  - See attached raw sequence listing error report.
  - APPLICANT MUST PROVIDE:
    - An initial or substitute paper copy or compact disc of the "Sequence Listing," as well as an amendment directing its entry into the specification.
- For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:
  - For Rules Interpretation, call (703) 308-4216
  - To Purchase Patentin Software, call (703) 306-2600
  - For Patentin Software Program Help, call (703) 306-4119 or e-mail at patin21help@uspto.gov or patin3help@uspto.gov
  - Additional claim fees of \$204 as a non-small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.

### SUMMARY OF FEES DUE:

Total additional fees required for this application is \$334 for a Large Entity:

- \$130 Late oath or declaration Surcharge.
- Total additional claim fee(s) for this application is \$204
  - \$168 for 8 independent claims over 3.
  - \$36 for 16 total claims over 20.

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

A copy of this notice **MUST** be returned with the response.

JOHN L ANDERSON

Telephone: (703) 308-9116

### PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO	INTERNATIONAL APPLICATION NO.	ATTY DOCKET NO
10/069,290	PCT/JP00/05617	350292001300 ;



# RAW SEQUENCE LISTING ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: 10/069,290Source: 04/0Date Processed by STIC: 3/2/2002

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS. PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:

- 1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,
- 2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY

FOR CRF SUBMISSION QUESTIONS, PLEASE CONTACT MARK SPENCER, 703-308-4212.

FOR SEQUENCE RULES INTERPRETATION, PLEASE CONTACT ROBERT WAX, 703-308-4216. PATENTIN 2.1 e-mail help: patin21help@uspto.gov or phone 703-306-4119 (R. Wax) PATENTIN 3.0 e-mail help: patin3help@uspto.gov or phone 703-306-4119 (R. Wax)

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER VERSION 3.1 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:

http://www.uspto.gov/web/offices/pac/checker

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail. Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom.

Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

- 1. EFS-Bio (<a href="http://www.uspto.gov/ebc/efs/downloads/documents.htm">http://www.uspto.gov/ebc/efs/downloads/documents.htm</a>>, EFS Submission User Manual ePAVE)
- 2. U.S. Postal Service: U.S. Patent and Trademark Office, Box Sequence, P.O. Box 2327, Arlington, VA 22202
- 3. Hand Carry directly to:
  - U.S. Patent and Trademark Office, Technology Center 1600, Reception Area, 7<sup>th</sup> Floor, Examiner Name, Sequence Information, Crystal Mall One, 1911 South Clark Street, Arlungton, VA 22202
  - U.S. Patent and Trademark Office, Box Sequence, Customer Window, Lobby, Room 1B03, Crystal Plaza Two, 2011 South Clark Place, Arlington, VA 22202
- 4. Federal Express, United Parcel Service, or other delivery service to: U.S. Patent and Trademark Office, Box Sequence, Room 1B03-Mailroom, Crystal Plaza Two, 2011 South Clark Place, Arlington, VA 22202

Revised 01/29/2002

### Raw Sequence Listing Error Summary

ERROR DETECTED	SUGGESTED CORRECTION SERIAL NUMBER: 10,1069,290
ATTN: NEW RULES CASES	: Please disregard english "Alpha" headers, which were inserted by Pto Software
1Wrapped Nucleics Wrapped Aminos	The number/text at the end of each line "wrapped" down to the next line. This may occur if your file was retrieved in a word processor after creating it. Please adjust your right margin to 3; this will prevent "wrapping."
2Invalid Line Length	The rules require that a line not exceed 72 characters in length. This includes white spaces.
3Misaligned Amino Numbering	The numbering under each 5th amino acid is misaligned. Do not use tab codes between numbers; use space characters, instead.
4Non-ASCII	The submitted file was not saved in ASCII(DOS) text, as required by the Sequence Rules. Please ensure your subsequent submission is saved in ASCII text.
5Variable Length	Sequence(s)contain n's or Xaa's representing more than one residue. Per Sequence Rules, each n or Xaa can only represent a alngle residue. Please present the maximum number of each residue having variable length and indicate in the <220>-<223> section that some may be missing.
6Patentin 2.0 "bug"	A "bug" in Patentin version 2.0 has caused the <220>-<223> section to be missing from amino acid sequences(s) Normally, Patentin would automatically generate this section from the previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section to the subsequent amino acid sequence. This applies to the mandatory <220>-<223> sections for Artificial or Unknown sequences.
7Skipped Sequences (OLD RULES)	Sequence(s) missing. If intentional, please insert the following lines for each skipped sequence:  (2) INFORMATION FOR SEQ ID NO:X: (insert SEQ ID NO where "X" is shown)  (i) SEQUENCE CHARACTERISTICS: (Do not insert any subheadings under this heading)  (xi) SEQUENCE DESCRIPTION:SEQ ID NO:X: (insert SEQ ID NO where "X" is shown)  This sequence is intentionally skipped
	Please also adjust the "(ii) NUMBER OF SEQUENCES:" response to Include the skipped sequences.
Skipped Sequences     (NEW RULES)	Sequence(s) missing. If Intentional, please insert the following lines for each skipped sequence. <210> sequence id number <400> sequence id number 000
9Use of n's or Xaa's (NEW RULES)	Use of n's and/or Xaa's have been detected in the Sequence Listing. Per 1.823 of Sequence Rules, use of <220>-<223> is MANDATORY if n's or Xaa's are present. In <220> to <223> section, please explain location of n or Xaa; and which residue n or Xaa represents.
10Invalid <213> Response	Per 1.823 of Sequence Rules, the only valid <213> responses are: Unknown, Artificial Sequence, or scientific name (Genus/species). <220><223> section is required when <213> response is Unknown or is Artificial Sequence.
Use of <220>	Sequence(s)missing the <220> "Feature" and associated numeric identifiers and responses.  Use of <220> to <223> is MANDATORY if <213> "Organism" response is "Artificial Sequence" or "Unknown." Please explain source of genetic material in <220> to <223> section.  (See "Federal Register," 06/01/1998, Vol. 63, No. 104, pp. 29631-32) (Sec. 1.823 of Sequence Rules)
12Patentin 2.0 "bug"	Please do not use "Copy to Disk" function of Patentin version 2.0. This causes a corrupted file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing). Instead, please use "File Manager" or any other manual means to copy file to floppy disk.
13Misuse of n	n can only be used to represent a single nucleotide in a nucleic acid sequence. N is not used to represent any value not specifically a nucleotide.
	AVCAGE Bioschmology Systems Branch = 08/21/2001